



IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Atty. Docket No.: 6794A-000032/US/DVD  
(3091/04/DIV/2)

Len F. LEE et al.

Serial No.: 10/830,125

Group Art Unit: TBA

Filed: April 23, 2004

Examiner: TBA

For: Novel Benzothiepinines Having Activity as Inhibitors of Ileal Bile Acid  
Transport and Taurocholate Uptake

**INFORMATION DISCLOSURE STATEMENT**

U.S. Patent and Trademark Office  
220 20th Street S, Customer Window  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, VA 22202

August 30, 2004

Sir:

Pursuant to their duty of good faith and candor as set forth in 37 C.F.R. §§ 1.56(a), 1.97 and 1.98 *et seq.*, Applicants submit herewith the attached Form PTO/SB/08A. Each of the references cited on the attached Form PTO/SB/08A was cited in parent application Serial No. 10/068,297. A copy of these references can be found in the file of parent application Serial No. 10/068,297. Applicants respectfully request that the Examiner consider and enter all the documents cited on the enclosed Form PTO/SB/08A into the file of the above-identified application. Applicants also request an indication of the same by return of the Form PTO/SB/08A being initialed and dated by the Examiner.

No fees are believed due to ensure consideration of the attached documents by the Examiner. However, if any fees are required or an overpayment of fees made, the Commissioner is hereby authorized to debit or credit our Deposit Account No. 19-0733, as necessary.

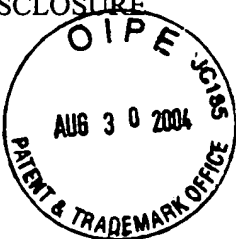
Respectfully submitted,

HARNESS, DICKY, & PIERCE, P.L.C.

By Ajay Pathak 8/30/2004  
Ajay Pathak, Reg. No. 38,266

P.O. Box 8910  
Reston, Virginia 20195  
(703) 668-8000

Enclosure:  
Form SB/08A

USPTO Form 1449 (modified) Patent and Trademark Office <b>INFORMATION DISCLOSURE CITATION</b> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin-top: 10px;">Page 1 of 11</div> <div style="text-align: center; margin-top: 20px;">  </div>	Attorney Docket No. 6794A-000032/US/DVD (3091/04/US/DVD)	Serial No. 10/830,125
Applicant(s): LEE et al		
Filing Date: April 23, 2004		Examiner: TBA Group: TBA

### U.S. PATENT DOCUMENTS

Examiner Initial	Doc Tab No.	Patent No.	Date	Name	Class	Subclass	Filing Date (if appropriate)
**	1	3,262,850	07/26/66	Glynne			
**	2	3,287,370	11/22/66	Mohrbacher			
**	3	3,389,144	06/18/68	Mohrbacher			
**	4	3,520,891	07/21/70	Mohrbacher			
**	5	3,674,836	07/04/72	Creger			
**	6	3,692,895	09/19/72	Nelson			
**	7	3,714,190	01/30/73	Boissier			
**	8	3,781,328	12/25/73	Witte			
**	9	3,948,973	04/06/76	Phillips			
**	10	3,962,261	06/08/76	Zinnes			
**	11	3,972,878	08/03/76	Schirmann			
**	12	3,983,140	09/28/76	Endo			
**	13	4,002,750	01/11/77	Ambrogi			
**	14	4,058,552	11/15/77	Mieville			
**	15	4,185,109	01/22/80	Rosen			
**	16	4,231,938	11/04/80	Monaghan			
**	17	4,251,526	02/17/81	McCall			
**	18	4,346,227	08/24/82	Terahara			
**	19	4,444,784	04/24/84	Hoffman			
**	20	4,559,332	12/17/85	Grob			
**	21	5,075,293	12/24/91	Reifschneider			
**	22	5,153,184	10/06/92	Reifschneider			
**	23	5,158,943	10/27/92	Sohda			
**	24	5,244,887	09/14/93	Straub			
**	25	5,260,316	11/09/93	Van Duzer			
**	26	5,334,600	08/02/94	Van Duzer			
**	27	5,350,761	09/27/94	Van Duzer			
**	28	5,354,772	10/11/94	Kathawala			
**	29	5,430,116	07/04/95	Kramer			
**	30	5,502,045	03/26/96	Miettinen			
**	31	5,512,558	04/30/96	Enhnen			
**	32	5,519,001	05/21/96	Rampratap			
**	33	5,602,152	02/11/97	Berthelon			
**	34	5,610,151	03/11/97	Glombik			
**	35	5,663,165	09/02/97	Brieaddy			
**	36	5,703,188	12/30/97	Mandeville			
**	37	5,705,524	01/06/98	McGee			
**	38	5,723,458	03/03/98	Brieaddy			
**	39	5,767,115	06/16/98	Rosenblum			

USPTO Form 1449 (modified) U.S. Department of Commerce Patent and Trademark Office <b>INFORMATION DISCLOSURE CITATION</b> <div>Page 2 of 11</div>				Attorney Docket No. 6794A-000032/US/DVD (3091/04/US/DVD)		Serial No. 10/830,125		
				Applicant(s): LEE et al				
				Filing Date: April 23, 2004		Examiner: TBA Group: TBA		
**	40	5,929,062	07/27/99	Haines				
**	41	5,994,391	11/30/99	Lee				
**	42	6,020,330	02/01/00	Enhssen				
**	43	6,034,118	03/07/00	Bischofberger				
<b>FOREIGN PATENT DOCUMENTS</b>								
Examiner Initial		Document No.	Date	Country	Class	Subclass	Translation	
							YES	NO
**	44	AU-A-30209/92	12/17/92	Australia				X
**	45	AU-A-61946/94	06/05/94	Australia				X
**	46	AU-A-61948/94	06/05/94	Australia				X
**	47	AU-A-61949/94	06/05/94	Australia				X
**	48	2,025,294	03/15/91	Canada				
**	49	2,078,588	03/22/93	Canada				
**	50	2,085,782	06/21/93	Canada				
**	51	2,085,830	06/21/93	Canada				
**	52	0 067 086	10/05/82	Europe				
**	53	0 129 748	02/01/85	Europe				
**	54	0 250 265	06/19/87	Europe				
**	55	0 338 331	06/04/89	Europe				
**	56	0 379 161	01/17/90	Europe				
**	57	0 508 425 A1	09/04/92	Europe				
**	58	0 526 402 A1	02/03/93	Europe				
**	59	0 531 901 A2	02/09/92	Europe				
**	60	0 549 967 A1	12/17/92	Europe				
**	61	0 559 064 A2	02/24/93	Europe				
**	62	0 563 731 A1	03/22/93	Europe				
**	63	0 568 898 A1	04/27/93	Europe				
**	64	0 796 846 A1	07/03/97	Europe				X
**	65	0 801 060 A1	15/10/97	Europe				
**	66	0 818 197 A1	06/25/97	Europe				X
**	67	0 818 448 A1	06/24/97	Europe				X
**	68	2 661 676-A1	02/05/90	France				
**	69	196 27 430 A1	08/07/96	Germany				X
**	70	1211258	02/01/68	Germany				
**	71	10-287662	10/27/98	Japan				X
**	72	89/01477	02/23/89	PCT			Abst	
**	73	91/08205	06/13/91	PCT			Abst	
**	74	92/17467	10/15/92	PCT			Abst	
**	75	92/18115	10/29/92	PCT			Abst	
**	76	92/18462	10/29/92	PCT			Abst	
**	77	93/16055	08/19/93	PCT			Abst	

USPTO Form 1449 (modified) U.S. Department of Commerce Patent and Trademark Office <b>INFORMATION DISCLOSURE CITATION</b> <div style="border: 1px solid black; padding: 2px; width: fit-content;">Page 3 of 11</div>				Attorney Docket No. 6794A-000032/US/DVD (3091/04/US/DVD)		Serial No. 10/830,125	
				Applicant(s): LEE et al			
				Filing Date: April 23, 2004		Examiner: TBA Group: TBA	
**	78	93/21146	10/28/93	PCT			Abst
**	79	94/18183	08/18/94	PCT			Abst
**	80	94/18184	08/18/94	PCT			Abst
**	81	94/24087	10/27/94	PCT			Abst
**	82	95/21843	08/17/95	PCT			Abst
**	83	96/05188	02/22/96	PCT			Abst
**	84	96/08484	03/21/96	PCT			Abst
**	85	96/16051	05/30/96	PCT			Abst
**	86	96/40255	12/19/96	PCT			Abst
**	87	97/03953	02/02/97	PCT			Abst
**	88	97/33882	09/18/97	PCT			Abst
**	89	97/49387	12/31/97	PCT			Abst
**	90	97/49736	12/31/97	PCT			Abst
**	91	98/02432	01/22/98	PCT			Abst
**	92	98/06405	02/19/98	PCT			Abst
**	93	98/23593	06/04/98	PCT			Abst
**	94	98/35937	08/20/98	PCT			Abst
**	95	98/38182	09/03/98	PCT			Abst
**	96	98/39299	09/11/98	PCT			Abst
**	97	98/40375	09/17/98	PCT			Abst
**	98	98/56757	12/17/98	PCT			Abst
**	99	99/11259	03/11/99	PCT			
**	100	99/11260	03/11/99	PCT			
**	101	99/11263	03/11/99	PCT			
**	102	99/14174	03/25/99	PCT			Abst
**	103	99/14204	03/25/99	PCT			
**	104	99/14215	03/25/99	PCT			Abst
**	105	99/32478	07/01/99	PCT			
**	106	99/35135	07/15/99	PCT			
**	107	99/64409	12/16/99	PCT			Abst
**	108	00/35889	06/22/00	PCT			Abst
**	109	2 305 665	04/16/97	United Kingdom			
**	110	2 329 334	03/24/99	United Kingdom			
<b>OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)</b>							
**	111	A. Barrett et al., "Total Synthesis and Stereochemical Assignment of the Quinquecyclopropane-Containing Cholesteryl Ester Transfer Protein Inhibitor U-106305", J. Am Chem. Soc., 1996, 118, pgs. 7863-7864					
**	112	P. Barter et al. "High Density Lipoproteins and Coronary Heart Disease", Atherosclerosis, 121 1996, pgs. 1-12.					
**	113	A. Beckwith et al., "Iododediazoniation of Arenediazonium Salts Accompanied by Aryl Radical Ring Closure" J. Org. Chem. 1987, Vol. 52, pgs. 1922-1930					

USPTO Form 1449 (modified) Patent and Trademark Office <b>INFORMATION DISCLOSURE CITATION</b> <div style="border: 1px solid black; padding: 2px; width: fit-content;">Page 4 of 11</div>		U.S. Department of Commerce  Attorney Docket No. 6794A-000032/US/DVD (3091/04/US/DVD)		Serial No. 10/830,125	
		Applicant(s): LEE et al			
		Filing Date: April 23, 2004			Examiner: TBA Group: TBA
**	114	D. Bilheimer et al., "Mevinolin and Colestipol Stimulate Receptor-Mediated Clearance of Low Density Lipoprotein From Plasma In Familial Hypercholesterolemia Heterozygotes", Proc. Natl. Acad. Sci. USA, Vol. 80, July 1983, pgs. 4124-4128			
**	115	C. Bisgaier et al., "Cholesteryl Ester Transfer Protein Inhibition By PD 140195, Lipids, Vol. 29, No. 12, 1994, pgs. 811-818			
**	116	D. Blankenhorn et al., "Beneficial Effects of Combined Colestipol-Niacin Therapy On Coronary Atherosclerosis and Coronary Venous Bypass Grafts", JAMA, June 19, 1987, Vol. 257, No. 23, pgs. 3233-3240			
**	117	D. Blankenhorn et al., "Beneficial Effects of Colestipol-Niacin Therapy on the Common Carotid Artery" Circulation Vol. 88, 1 July 1993, pgs. 20-28			
**	118	P. Bonin et al., "A Peptide Inhibitor Of Cholesteryl Ester Transfer Protein Identified By Screening a Bacteriophage Display Library", Journal of Peptide Research, 51, 1998, pgs. 216-225			
**	119	G. Brown, et al., "Regression of Coronary Artery Disease As A Result of Intensive Lipid-Lowering Therapy in Men With High Levels Of Apolipoprotein B", The New England Journal of Medicine, Volume 323, November 8, 1990, Number 19, pgs. 1289-1339.			
**	120	M. Brown et al., "Induction of 3-hydroxy-3Methylglutaryl Coenzyme A Reductase Activity in Human Fibroblasts Incubated with Compactin (ML-236B), A Competitive Inhibitor of the Reductase, The Journal of Biological Chemistry, Vol. 253, No. 4, February 22, 1978, pgs. 1121-1128			
**	121	S. Busch et al., "Cholesteryl Ester Analogs Inhibit Cholesteryl Ester But Not Triglyceride Transfer Catalyzed By The Plasma Cholesteryl Ester-Triglyceride Transfer Protein", Lipids, Vol. 25, No. 4 (1990), pgs. 216-220			
**	122	C. Camoutsis et al., "N-Substituted 4, 5-Dihydro-1, 2-Benzothiazepin-3-One 1, 1-Dioxide", J. Heterocyclic Chem. 17, pgs.1135-1136 (1980)			
**	123	L. Cashin-Hemphill et al., "Beneficial Effects of Colestipol-Niacin on Coronary Atherosclerosis A 4-Year Follow-up", JAMA, December 19, 1990, Vol. 264, No. 23, pgs. 3013-3017			
**	124	P. Catsoulacos et al., "Synthesis of Some N-Substituted 4,5-Dihydro-7,8-dimethoxybenzothiazepin-3-one 1,1-Dioxides", J. Heterocyclic Chem., Vol. 13 (1976), pgs. 1309-1314			
**	125	P. Catsoulacos et al., "Thiazo Compounds. Derivatives of 4, 5-Dihydro-7, 8-Dimethoxybenzothiazepin-3 one 1, 1-Dioxides", Journal of Chemical and Engineering Data, Vol. 22, No. 3, 1977, pgs. 353-354			
**	126	K. Cho et al, "A Peptide From Hog Plasma that Inhibits Human Cholesteryl Ester Transfer Protein", Biochimica et Biophysica Acta, 1391, 1998, pgs. 133-144			
**	127	D. Connolly et al., "Inactivation of Cholesteryl Ester Transfer Protein by Cysteine Modification", Biochemical and Biophysical Research Communications 223, pgs. 42-47, 1996			
**	128	S. Coval et al., "Wiedendiol-A and-B, Cholesteryl Ester Transfer Protein Inhibitors From The Marine Sponge Xestosponga Wiedenmayeri", Bioorganic & Medicinal Chemistry Letter, Vol. 5, No. 6, pgs. 605-610, 1995			
**	129	J. Davignon et al., "Apolipoprotein E and Atherosclerosis: Quest for an APO E Receptor Defect Leads to the Discovery of Pseudo Type III Dyslipoproteinemia in a Family", Atherosclerosis IX, pgs. 199-203			

USPTO Form 1449 (modified) Patent and Trademark Office <b>INFORMATION DISCLOSURE</b> <b>CITATION</b> <div style="border: 1px solid black; padding: 2px; width: fit-content;">Page 5 of 11</div>		U.S. Department of Commerce  Attorney Docket No. 6794A-000032/US/DVD (3091/04/US/DVD)	Serial No. 10/830,125
		Applicant(s): LEE et al	
		Filing Date: April 23, 2004	Examiner: TBA Group: TBA
**	130	J. Davignon et al., "Comparative Efficacy and Safety of Pravastatin, Nicotinic Acid and The Two Combined in Patients with Hypercholesterolemia", The American Journal of Cardiology, February 15, 1994, pgs. 339-345	
**	131	C. East et al., "Combination Drug Therapy for Familial Combined Hyperlipidemia", Annals of Internal Medicine, July 1, 1988, pgs. 25-32	
**	132	J. Emmerich et al., "Efficacy and Safety of Simvastatin (Alone or in Association with Cholestyramine) A 1 yr. Study in 66 Patients with Type II Hyperlipoproteinaemia", European Heart Journal (1990), 11, pgs. 149-155	
**	133	D. Erkelens, "Combination Drug Therapy with HMG Co A Reductase Inhibitors and Bile Acid Sequestrants for Hypercholesterolemia", Cardiology, 1990, 77, (suppl 4). pgs. 33-38	
**	134	H. Ginsberg, "Update on the Treatment of Hypercholesterolemia, with a Focus on HMG-CoA Reductase Inhibitors and Combination Regimens", Clinical Cardiology 18, pgs. 307-315, (1995)	
**	135	C. Glueck et al., "Gemfibrozil-Lovastatin Therapy for Primary Hyperlipoproteinemias" The American Journal of Cardiology, July 1, 1992, Vol. 70, No. 1, pgs. 1-9	
**	136	S. Grundy et al., "Influence of Combined Therapy with Mevinolin and Interruption of Bile-Acid Reabsorption on Low Density Lipoproteins in Heterozygous Familial Hypercholesterolemia", Annals of Internal Medicine, 1985, 103: pgs. 339-343	
**	137	H. Gylling et al., "Effects Of Inhibiting Cholesterol Absorption And Synthesis On Cholesterol And Lipoprotein Metabolism In Hypercholesterolemic Non-Insulin-Dependent Diabetic Men", Journal of Lipid Research, Volume 37, 1996, pgs. 1776-1785	
**	138	E. Haber, "Molecular Cardiovascular Medicine" Scientific American, pgs. 35-40	
**	139	V. Hegde et al., "A Depsipeptide Fungal Metabolite Inhibitor Of Cholesteryl Ester Transfer Protein", Bioorganic & Medicinal Chemistry Letters 8, 1998, pgs. 1277-1280	
**	140	L. Hellberg et al., "5a-Hydroxy-3a-Cholestanecarboxylic" The New Journal for Organic Synthesis", Vol. 15, Number 1-2, February-April 1983, pgs. 154-156	
**	141	J. Heubi et al., "Primary Bile Acid Malabsorption: Defective In Vitro Ileal Active Bile Acid Transport", Gastroenterology 1982, 83: pgs. 804-11	
**	142	N. Hoogerbrugge et al., "The Additional Effects of Acipimox To Simvastatin In The Treatment of Combined Hyperlipidaemia", Journal of Internal Medicine, 1997, 241: pgs. 151-155	
**	143	N. Hoogerbrugge et al., "The Efficacy and Safety of Pravastatin, Compared To And In Combination With Bile Acid Binding Resins, In Familial Hypercholesterolaemia", Journal of Internal Medicine 1990, 228; pgs. 261-266	
**	144	A. Hutchesson et al., "Dual Bezafibrate-Simvastatin Therapy For Combined Hyperlipidaemia", Journal of Clinical Pharmacy and Therapeutics 1994, 19, pgs. 387-389	
**	145	T. Ichihashi, "Mechanism of Hypocholesterolemic Action of S-8921 in Rats: S-8921 Inhibits Ileal Bile Acid Absorption", The Journal Of Pharmacology And Experimental Therapeutics, Vol. 284, No. 1, pgs. 43-50	
**	146	D. Illingworth, et al., "Influence of Lovstatin plus Gemfibrozil on Plasma Lipids and Lipoproteins in Patients With Heterozygous Familial Hypercholesterolemia", Circulation Vol. 79, Number 3, March 1989, 590-596	
**	147	D. Illingworth, "Mevinolin Plus Colestipol in Therapy for Severe Heterozygous Familial Hypercholesterolemia", Annals of Internal Medicine, 1984; 101, pgs. 598-604	

USPTO Form 1449 (modified) Patent and Trademark Office <b>INFORMATION DISCLOSURE CITATION</b> <div style="border: 1px solid black; padding: 2px; width: fit-content;">Page 6 of 11</div>		U.S. Department of Commerce  Attorney Docket No. 6794A-000032/US/DVD (3091/04/US/DVD)		Serial No. 10/830,125	
		Applicant(s): LEE et al			
		Filing Date: April 23, 2004			Examiner: TBA Group: TBA
**	148	International Search Report mailed May 23, 2000 based on PCT/US 99/27942			
**	149	International Search Report mailed May 23, 2000 based on PCT/US 99/27943			
**	150	International Search Report mailed May 23, 2000 based on PCT/US 99/27944			
**	151	International Search Report mailed May 23, 2000 based on PCT/US 99/27945			
**	152	International Search Report mailed May 18, 2000 based on PCT/US 99/27947			
**	153	International Search Report mailed May 15, 2000 based on PCT/US 99/27948			
**	154	International Search Report mailed May 17, 2000 based on PCT/US 99/27949			
**	155	J. Kane, et al., "Regression of Coronary Atherosclerosis During Treatment of Familial Hypercholesterolemia With Combined Drug Regimens", JAMA, December 19, 1990, Chapter 26, Vol. 264, No. 23, pgs. 3007-3012			
**	156	A. Katritzky et al., "Preparation Of 6-7- And 8-Membered Sultams By Friedel-Crafts Cyclization Of w-Phenylalkanesulfamoyl Chlorides", Organic Preparations and Procedures Int., 24 (4), pgs. 463-467 (1992)			
**	157	T. Kazumi et al., "Effects of Niceritrol On Elevated Serum Lipoprotein LP (A) Levels in Diabetic Patients With Or Without Overt Proteinuria", Current Therapeutic Research, Vol. 55, No. 5, May 1994, pgs. 546-551			
**	158	W. Kramer, et al., "Intestinal Bile Acid Absorption", The Journal of Biological Chemistry". Vol. 268, No. 24 Issue of August 25, pgs. 18035-18046, 1993			
**	159	Kuo, M.S. et al., "Discovery, Isolation, Structure Elucidation, and Biosynthesis of U-106305, a Cholesteryl Ester Transfer Protein Inhibitor from UC 11136", J. Am. Chem. Soc. 117, pp. 10629-10634 (1995)			
**	160	Kvis, K. et al. , "Benzocycloheptenes and Heterocyclic Analogues as Potential Drugs. VII, 4-Phenyl-,3,4,5-Tetrahydro-1-Benzothiepins and Some Related Compounds", Chem. Commun./Vo.37/(1973) pgs. 3808-3816			
**	161	Lee, J.C. et al., "A Cholesteryl Ester Transfer Protein Inhibitor from an Insect-associated Fungus", The Journal of Antibiotics 49(7), pp. 693-696			
**	162	A.M. Lees et al., "Therapy of Hypercholesterolemia With Mevinolin And Other Lipid-Lowering Drugs", Arteriosclerosis 6, 1986, pg. 544a			
**	163	T. Leren et al., "Effects of Lovastatin Alone and In Combination with Cholestyramine on Serum Lipids and Apolipoproteins in Heterozygotes for Familial Hypercholesterolemia", International Journal for Research and Investigation on Atherosclerosis and Related Diseases, 73, (1988), pgs. 135-141			
**	164	M. Lewis, et al., "Effects Of 2164U90 on Ileal Bile Acid Absorption and Serum Cholesterol in Rats and Mice, Journal of Lipid Research, Vol. 36, 1995,pgs. 1098-1105			
**	165	R. Lewis, Hawley's Condensed Chemical Dictionary, pg. 1238			
**	166	W. Ling et al., "Minireview Dietary Phytosterols A Review of Metabolism, Benefits and Side Effects", Life Sciences, Vol. 57, No. 3, 1995, pgs. 195-206			
**	167	H. Mabuchi et al., "Reduction of Serum Cholesterol In Heterozygous Patients with Familial Hypercholesterolemia", The New England Journal of Medicine, Vol. 308, March 17, 1983,pgs. 609-613			
**	168	M. Malloy et al., "Complementarity of Colestipol, Niacin, and Lovastatin in Treatment of Severe Familial Hypercholesterolemia", Annals of Internal Medicine 1987; 107: pgs. 616-623			

USPTO Form 1449 (modified) Patent and Trademark Office		U.S. Department of Commerce		Attorney Docket No. 6794A-000032/US/DVD (3091/04/US/DVD)		Serial No. 10/830,125			
INFORMATION DISCLOSURE CITATION <div style="border: 1px solid black; padding: 2px; width: fit-content;">Page 7 of 11</div>				Applicant(s): LEE et al					
				Filing Date: April 23, 2004				Examiner: TBA Group: TBA	
**	169	W. Mandeville et al., "Bile Acid Sequestrants: Their Use In Combination With Other Lipid-Lowering Agents, Idrugs 1999 Vol. 2., No. 3, pgs. 237-242							
**	170	G. Marais et al., "Rhabdomyolysis and Acute Renal Failure Induced by Combination Lovastatin and Gemfibrozil Therapy", Annals of Internal Medicine, February 1, 1990, Volume 112, Number 3, pgs. 228-230							
**	171	P. McCarthy, "New Approaches to Atherosclerosis: An Overview", Medicinal Research Reviews, Vol. 13, No. 2, 1993, pgs. 139-159							
**	172	R. Morton, "Regulation of Lipid Transfer Between Lipoproteins By An Endogenous Plasma Protein: Selective Inhibition Among Lipoprotein Classes, Journal of Lipid Research, Vol. 35, 1994, pgs. 836-847							
**	173	F. Nerdel et al., "Quartermay Salts of B-Amino Aldehydes and B-Iodoaldehydes", Chemische Berichte (Ed. H. Zahn), Vol. 98 (1965), pgs. 728-734							
**	174	M. Newman et al., "The Conversion of Phenols to Thiophenols via Dialkylthiocarbamates", The Journal Of Organic Chemistry, Vol. 31, September-December 1966, pgs. 3980-3984							
**	175	A. Orahovats et al., "A Ring Enlargement from Seven-to Ten-Membered-Ring Sulfonamide Derivatives", Helvetica Chimica Acta, Vol. 79, (1996), pgs. 1121-1128							
**	176	H. Pan et al., "Pharmacokinetics and Pharmacodynamics of Pravastatin Alone and With Cholestyramine in Hypercholesterolemia", Clin. Pharmacol Ther. (1980) 9, 313, pgs. 201-207							
**	177	N. Panagiotopoulos et al., "N(P-Bromophenyl) -4,5 - Dihydro -7, 8 - Dimethoxy Benzothiazepine - ONE 1, 1-Dioxide C17 H16 brNO5S", Cryst. Struct. Comm. (1980) 9, pgs. 313-319							
**	178	R. Pasternak et al., "Effect of Combination Therapy with Lipid-Reducing Drugs in Patients with Coronary Heart Disease and "Normal" Cholesterol Levels", Annals of Internal Medicine, October 1, 1996, Vol. 125, Number 7, pgs. 529-538							
**	179	R. Patra et al., "Conformational and Steric Requirements Of The Side Chain For Sulphur Participation In Benzthiepin Derivatives", Tetrahedron Letters, Vol. 30, No. 32, pgs. 4279-4282, 1989							
**	180	R. Pierce et al., "Myopathy and Rhabdomyolysis Associated With Lovastatin-Gemfibrozil Combination Therapy, JAMA, July 4, 1990, Vol. 264, No. 1, pgs. 71-75							
**	181	W. Pirkle et al., "Trichlorosilane-Induced Cleavage. A Mild Method for Retrieving Carbinols From Carbamates", Journal Organic Chemistry, Vol. 42, No. 15, 1977, pgs. 2781-2782							
**	182	W. Pirkle et al., "Dynamic NMR Studies of Disatereomeric Carbamates: Implications toward the Determination of Relative Configuration by NMR" Journal of Organic Chemistry, Vol. 44, No. 26, 1979, pgs. 4891-4896							
**	183	W. Pirkle et al., "An Example of Automated Liquid Chromatography Synthesis of a Broad-Spectrum Resolving Agent and Resolution of 1-(Naphthyl) 2, 2, 2-Trifluoroethanol", The Journal of Organic Chemistry Volume 39, No. 26, 1974, pgs. 3904-3906							
**	184	T. Pietzonka et al., "Phosphonate-Containing Analogs Of Cholesteryl Ester As Novel Inhibitors Of Cholesteryl Ester Transfer Protein", Bioorganic & Medicinal Chemistry Letters, Vol. 6, No. 16, pgs. 1951-1954							
**	185	Pravastatin Multicenter Study Group II, "Comparative Efficacy and Safety of Pravastatin and Cholestyramine Alone And Combined in Patients With Hypercholesterolemia", Archives of Internal Medicine, Vol. 153, June 14, 1993, pgs. 1321-1328							



USPTO Form 1449 (modified) Patent and Trademark Office		U.S. Department of Commerce	Attorney Docket No. 6794A-000032/US/DVD (3091/04/US/DVD)	Serial No. 10/830,125
INFORMATION DISCLOSURE CITATION			Applicant(s): LEE et al	
Page 8 of 11			Filing Date: April 23, 2004	Examiner: TBA Group: TBA
**	186	E. Reihner et al., "Regulation of Hepatic Cholesterol Metabolism In Humans: Stimulatory Effects of Cholestyramine on HMG-CoA Reductase Activity and Low Density Lipoprotein Receptor Expression In Gallstone Patients, Journal of Lipid Research, Volume 31, 1990, pgs. 2219-2226		
**	187	R. Remick et al., "Comparison of Fluoxetine and Desipramine In Depressed Outpatients", Therapeutic Research, Vol. 53, No. 5, May 1993, pgs. 457-483		
**	188	S. Rosenblum et al., "Discovery of 1-(4-Fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2-azetidinone (SCH 58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption, Journal of Medicinal Chemistry, 1998, Vol. 41, No. 6, pgs. 973-980		
**	189	G. Salem et al., "Benzothiazine and Benzothiazepine Derivatives: Structures of N-p-Bromophenyl-6, 7-Dimethoxy-1, 2-Benzothiazin-3(4H)-One 1, 1-Dioxide (BBTZ) and 4, 5-Dihydro-8,9-Dimethoxy-N-(5-Methyl-2-Pyridyl)-1,2-Benzothiazepin-3-One 1, 1-Dioxide (MPTE)", Acta Cryst. (1986) C42, pgs. 1581-1584		
**	190	J. Sasaki et al., "Effects of Fluvastatin, A New Inhibitor of HMG-CoA Reductase, and Niceritol on Serum Lipids, Lipoproteins and Cholesterol Ester Transfer Activity In Primary Hypercholesterolemic Patients", International Journal of Clinical Pharmacology and Therapeutics, Vol. 33, No. 7, 1995, pgs. 420-426		
**	191	K. Sindelar et al., "Neurotropic and Psychotropic Compounds. XXIX. Derivatives Of 2,3,4,5-Tetrahydro-1-Benzothiepin, Chemical Commun., Vol. 33, 1968, pgs. 4315-4327		
**	192	K. Sindelar et al., "Benzocycloheptenes and Heterocyclic Analogues As Potential Drugs. III. Further Synthetic Experiments In The Series Of 1-Benzothiepin Derivatives, Vol. 37, 1972, 1195-1206		
**	193	C. Sirtori, "New Targets For Lipid Lowering And Atherosclerosis Prevention", Pharmac. Ther. Vol. 67, No. 3., pgs. 433-447, 1995		
**	194	Y. Son, "Purification and Characterization of Human Plasma Proteins That Inhibit Lipid Transfer Activities", Biochimica et Biophysica Acta, 795, 1984, pgs. 473-480		
**	195	D. Sprecher et al., "Low-Dose Combined Therapy with Fluvastatin and Cholestyramine in Hyperlipidemic Patients", Ann Intern Med. 1994; 120: pgs. 537-543		
**	196	C.I. Stassinopoulou, et al., "C NMR Spectra of Benzothiazepinone, Benzothiazinone and Benzosulphonamide N-Substituted Derivatives" Department of Biology, Nuclear Research Center		
**	197	E. Stedronsky et al., "Interaction of Bile Acids and Cholesterol with Non-Systemic Agents Having Hypocholesterolemic Properties", Biochimica et Biophysica Acta., 1210, 1994, pgs. 255-287		
**	198	I. Stein, et al., "Effects of Simvastatin and Cholestyramine in Familial and Nonfamilial Hypercholesterolemia", Arch Intern Med. Vol. 150, February 1990, pgs. 341-345		
**	199	E. Stein, et al., "Lovastatin Alone And In Combination For Treatment Of Primary Hypercholesterolemia", Alan R. Liss, Inc. 1988, pgs. 281-293		
**	200	K. Suckling, et al., "Cholesterol Lowering and Bile Acid Excretion in the Hamster with Cholestyramine Treatment, Atherosclerosis, 89, (1991) pgs. 183-190		
**	201	T. Swenson, "Mechanism of Cholesteryl Ester Transfer Protein Inhibition by a Neutralizing Monoclonal Antibody and Mapping of the Monoclonal Antibody Epitope", The Journal of Biological Chemistry, Vol. 264, No. 24, Aug. 25, pgs. 14318-14326, 1989		

USPTO Form 1449 (modified) Patent and Trademark Office <b>INFORMATION DISCLOSURE CITATION</b> <div style="border: 1px solid black; padding: 2px; width: fit-content;">Page 9 of 11</div>		U.S. Department of Commerce  Attorney Docket No. 6794A-000032/US/DVD (3091/04/US/DVD)	Serial No. 10/830,125
		Applicant(s): LEE et al	
		Filing Date: April 23, 2004	Examiner: TBA Group: TBA
**	202	A. Tall, "Plasma Cholesteryl Ester Transfer Protein", Journal of Lipid Research", Volume 34, 1993, pgs. 1255-1274	
**	203	Y. Tamura et al., "Novel Conversions of Benzo [b] thiophen-3 (2-H)-ones into 1, 2-Benzisothiazole and Tetrahydro-1, 2-Benzothiazepin-5-One Systems via Sulphimide Intermediates, J.C.S. Perkin I, pgs. 2830-2834	
**	204	K. Thurmond et al., "Water-Soluble Knedel-like Structures: The Preparation of Shell-Cross-Linked Small Particles", Journal American Chemistry Soc. Vol., 118, No. 30, 1996, pgs. 7239-7240	
**	205	P. Tyle, "Tontophoretic Devices for Drug Delivery", Pharmaceutical Research, Vol. 3. No. 6 1986, pgs. 318-325	
**	206	M. Une et al., "Metabolism of 3a, 7a-Dihydroxy-7b-Methyl-5b-Cholanoic Acid and 3a, 7B-Dihydroxy-7a-Methyl-5B-Cholanoic Acid Hamsters, Biochimica et Biophysica Acta, 833 (1985), pgs. 196-202	
**	207	J. Vacek et al., "Comparison of Lavastatin (20 mg) and Nicotinic Acid (1.2g) With Either Drug Alone for Type II Hyperlipoproteinemia, The American Journal Of Cardiology, Vol. 76, July 15, 1995, pgs. 182-184	
**	208	M. Van Heck et al., "In Vivo Metabolism-Based Discovery of a Potent Cholesterol Absorption Inhibitor, SCH58235, in the Rat and Rhesus Monkey Through the Identification of the Active Metabolites of SCH48461", The Journal of Pharmacology and Experimental Therapeutics, Vol. 283, No. 1, pgs. 157-754	
**	209	G. Vega et al., "Treatment of Primary Moderate Hypercholesterolemia With Lovastatin (Mevinolin) and Colestipol", JAMA, Jan 2, 1987, Vol. 257, No. 1, pgs. 33-37	
**	210	G. Wess et al., "Synthesis and Biological Activity of Bile Acid-Derived HMG-CoA Reductase Inhibitors. The Role of 21-Methyl in Recognition of HMG-CoA Reductase and the Ileal Bile Acid Transport System", Journal Of Medicinal Chemistry" 1994, 37, pgs. 3240-3246	
**	211	J. Wetterau et al., "An MTP Inhibitor that Normalizes Atherogenic Lipoprotein Levels In WHHL Rabbits", Science Vol. 282, 10/23/98, pgs. 751-754	
**	212	O. Wiklund et al., "Pravastatin and Gemfibrozil Alone and in Combination for the Treatment of Hypercholesterolemia", The American Journal of Medicine Vol. 94, January 1993, pgs. 13-19	
**	213	S. Wirebaugh et al., "A Retrospective Review of the Use of Lipid-Lowering Agents in Combination, Specifically, Gemfibrozil and Lovastatin", Pharmacotherapy Vol. 12, Number 6, 1992, pgs. 445-450	
**	214	J. Witztum, "Drugs Used In The Treatment of Hyperlipoproteinemias", The Pharmacological Basis of Therapeutics, 9 <sup>th</sup> Edition, pgs. 875-894	
**	215	Yan Xia et al., "Substituted 1,3,5-Triazines As Cholesterol Ester Transfer Protein Inhibitors", Bioorganic & Medicinal Chemistry Letters, Vol. 6, No. 7, 1996, pgs. 919-922	
**	216	A. Yamamoto et al., "Effects of Probucol on Xanthomata Regression in Familial Hypercholesterolemia", Am Journal Cardiolgy, 1986, 57: pgs. 29H-35H	
**	217	K. Ytre-Arne et al., "Simvastatin and Cholestyramine In The Long-Term Treatment of Hypercholesterolaemia", Journal of Internal Medicine (1989): 226, pgs. 285-90	
EXAMINER		DATE CONSIDERED	

<div>USPTO Form 1449 (modified)      U.S. Department of Commerce</div> <div>Patent and Trademark Office</div> <div>INFORMATION DISCLOSURE</div> <div>CITATION</div> <div>Page 10 of 11</div>	<div>Attorney Docket No.</div> <div>6794A-000032/US/DVD</div> <div>(3091/04/US/DVD)</div>	<div>Serial No.</div> <div>10/830,125</div>	
	<div>Applicant(s): LEE et al</div>		
	<div>Filing Date: April 23, 2004</div>	<div>Examiner:</div> <div>TBA</div> <div>Group: TBA</div>	
<div>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.</div> <div>**Copies of references not provided at the time of this submission.</div>			

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(use as many sheets as necessary)*

Sheet	10	of	11
-------	----	----	----

**Complete if Known**

Application Number	10/830,125
Filing Date	April 23, 2004
First Named Inventor	LEE et al
Group Art Unit	TBA
Examiner Name	TBA
Attorney Docket Number	6794A-000032/US/DVD

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sub>6</sub>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	226.	DE	3 122 499	A1				
	227.	EP	0 022 487	A1				
	228.	EP	0 033 538	B1				
	229.	EP	0 244 364	A2				
	230.	EP	0 409 281	A1				
	231.	GB	1 211 258					
	232.	GB	2 077 264	A				
	233.	WO	98/38182					
	234.	WO	98/40375					

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

**Burden Hour Statement:** This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → +

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO  <h2 style="text-align: center; margin: 10px 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center; margin-top: 10px;">(use as many sheets as necessary)</p>		<h3 style="text-align: center; margin: 0;">Complete if Known</h3> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>10/830,125</td> </tr> <tr> <td>Filing Date</td> <td>April 23, 2004</td> </tr> <tr> <td>First Named Inventor</td> <td>Len F. LEE et al.</td> </tr> <tr> <td>Group Art Unit</td> <td>TBA</td> </tr> <tr> <td>Examiner Name</td> <td>TBA</td> </tr> <tr> <td>Attorney Docket Number</td> <td>6794A-000032/(US/DVD)</td> </tr> </table>		Application Number	10/830,125	Filing Date	April 23, 2004	First Named Inventor	Len F. LEE et al.	Group Art Unit	TBA	Examiner Name	TBA	Attorney Docket Number	6794A-000032/(US/DVD)
Application Number	10/830,125														
Filing Date	April 23, 2004														
First Named Inventor	Len F. LEE et al.														
Group Art Unit	TBA														
Examiner Name	TBA														
Attorney Docket Number	6794A-000032/(US/DVD)														
Sheet	11	of	11												

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	235.	Angelin, B., "Regulation of Hepatic Cholesterol Metabolism in Man," Ann. Med. 23, pp. 10-27 (1991).	
	236.	Blum, C. B., "Comparison of Properties of Four Inhibitors of 3-Hydroxy-3-Methylglutaryl-Coenzyme A Reductase," Am. J. Cardiol., 73(14), 3D-11D, (1994).	
	237.	Cayen, M.N., "Disposition, Metabolism and Pharmacokinetics of Anthyperlipidemic Agents in Laboratory Animals and Man," Pharmac. & Ther., 29, pp. 157-204 (1985).	
	238.	Da Col, et al., "Tolerability and Efficacy of Combination Therapy with Simvastatin Plus Gemfibrozil in Type II Refractory Familial Combined Hyperlipidemia," Curr. Therap. Research, Vol. 53, No. 5, pp. 473-483 (1993).	
	239.	Davignon, et al. "HMG CoA Reductase Inhibitors: A look back and a look ahead," Can. J. Cardiol., 8(8), pp. 843-864 (1992).	
	240.	Endo, A. "Chemistry, biochemistry and pharmacology of HMG-Co-A reductase inhibitors," Klin. Wochenschr. 66, pp. 421-427 (1988).	
	241.	Kramer et al., "Bile acid derived HMG-CoA reductase inhibitors," Biochimica et Biophysica Acta, 1227 pp. 137-154 (1994).	
	242.	Marcus, A., "Role of the HMG-CoA Reductase Inhibitors in the Treatment of Dyslipidemia: An Evolutionary Review," CVR&R, pp. 13-27 (January 1996).	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

8/30/04